EPA Registration File
87636-2

ENVIROLYTE

Aqueous Solution of Sodium Chloride

Envirolyte solutions:

- **are cost effective solutions to produce,**
- **can be produced for multiple industrial and commercial applications,**
- **can be produced with a controlled pH and concentration of Free Available Chlorine (FAC),**
- **are produced with low energy cost from water and salt (sodium chloride)**

ACTIVE INGREDIENT:

Hypochlorous Acid..... 0.105%

OTHER INGREDIENTS..... 99.895%

TOTAL..... 100.000%

Contains 1357 ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN

Reg. No. 87636- **Est. No. 87636-TX-001**

Manufactured by:
Universal Bacteria Specialist
PO Box 570324
Houston, Texas 77257
Ph: 281-342-9555 email cl@universalbacteriaspecialist.com

Envirolyte must be used within 30 days after being produced. DATE PRODUCED:_____

Container Size: (1 gallon, 5 gallon, 55 gallon, 275 gallon tote, 330 gallon tote, 660 gallon tote)

UNIVERSAL BACTERIA SPECIALIST

GENERAL

Envirolyte is produced through the electrolysis of sodium chloride in water. Hypochlorous acid, a weak acid, oxidizing agent, and antimicrobial agent, is produced at the anode. The product at the cathode is sodium hydroxide (lye). In this particular process, Envirolyte is produced at a pH of 6.5 between 6.01 and 8.16.

The properties of Envirolyte can be closely controlled by manipulation of multiple process factors, including the electrolytic cell potential, flow rate, and salt concentration.

Envirolyte will be produced and applied as a liquid with physical properties similar to water.

- Freezing point is 32° F
- Boiling point is 212°F
- Colorless
- Slight chlorine odor

Store Envirolyte in a closed, plastic container in a cool, dark area away from direct sunlight. Envirolyte product must be used within 30 days of production or the FAC (the free available chlorine) will decrease.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

OIL AND GAS APPLICATIONS

Frac Water – For typical water treatment, mix 5.0 gallons of Envirolyte with 995 gallons of frac water to 2.5 ppm FAC to mitigate and retard the growth of non-public health organisms such as anaerobic bacteria, aerobic bacteria, and sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Produced Waters – For typical treatment of produced water tanks, add 21 gallons of Envirolyte with 979 gallons of produced water to 10.5 ppm FAC while rolling volume of tank to retard the growth of non-public health organisms such as anaerobic bacteria, aerobic bacteria, and sulfate reducing bacteria.

Water Flood Injection Wells - For typical water treatment, mix 21 gallon of Envirolyte with 979 gallons of injection water to 10.5 ppm FAC to mitigate and retard the growth of non-public health organisms such as anaerobic bacteria, aerobic bacteria, sulfate reducing bacteria, and control pipeline slime.

UNIVERSAL BACTERIA SPECIALIST

Sour Wells- For typical well treatment, slug dose 168 gallons at 500 ppm FAC of Envirolyte at 550 ppm of Envirolyte on a daily or weekly basis to control non-public health microorganisms, reduce hydrogen sulfide gas, and microbial influenced corrosion (MIC).

Heater Treaters, Hydrocarbon Storage Facilities and Gas Storage Wells – For typical storage facility treatment mix 126 gallons of Envirolyte to 500 ppm FAC to flow through vessels into storage area to retard the growth of non-public health microorganisms, control the formation of hydrogen sulfide, and reduce corrosion of storage tanks.

Use Sites Associated with Gas and Oil Production

Oil and Gas Wells
Plants and Refineries
Pipelines
Hydraulic Fracturing

PRECAUTIONARY STATEMENTS

Physical or Chemical Hazards: Envirolyte is not compatible with other chemicals such as acids and hydrogen peroxide.

UNIVERSAL BACTERIA SPECIALIST

STORAGE AND DISPOSAL

Do not contaminate water,food, or feed by storage and disposal.

For industrial and commercial use packages:
Pesticide Storage: *Store in a closed dark plastic container in cool, dry area away from heat and* sunlight. Do not store with easily oxidizable materials, acids and reducers. In case of spill, isolate container (if possible) and flood area with large amounts of water to dissolve all material before discarding this container in trash.
Emergency Handling: In case of contamination or decomposition, do not reseal container. Isolate in open, well-ventilated area. Flood with large volume of water. Cool unopened containers in vicinity by water spray.

Pesticide Disposal: Pesticide wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the EPA Regional Office for guidance.

Small Packages (5 gallons or less):
Container Handling: Nonrefillable rigid container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay clear of smoke.

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Container Handling: REFILLABLE CONTAINER. Refill this container with Envirolyte only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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Pipelines
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OIL AND GAS APPLICATIONS

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UNIVERSAL BACTERIA SPECIALIST

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UNIVERSAL BACTERIA
SPECIALIST

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UNIVERSAL BACTERIA SPECIALIST

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UNIVERSAL BACTERIA SPECIALIST

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 11/25/2013	EPA Reg No./File Symbol 87636-	Page 1 of 3
Applicant's/Registrant's Name & Address Universal Bacteria Specialist, PO Box 570324, Houston, TX 77257	Product Envirolyte	

Ingredient Hypochlorous Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2600	Kuhn, J. (2004) Skin Sensitization Study in Guinea Pigs:	Not assigned	Universal Bacteria Specialist	own	
	Study ID. 17370-13 16 pages				
870.1100	Kuhn, J. (2013) Acute Oral Toxicity Study (UDP) in Rats	Not assigned	Universal Bacteria Specialist	own	
	Study ID 17365-13. 10 pages				
870.1200	Kuhn, J. (2013) Acute Dermal Toxicity Study in Rabbits	Not assigned	Universal Bacteria Specialist	own	
	Study ID 17366-13. 11 pages				
870.1300	Kuhn, J. (2013) Acute Inhalation Toxicity Study in Rats	Not assigned	Universal Bacteria Specialist	own	
	Study ID 17367-13. 17 pages				
870.2400	Kuhn, J. (2013) Acute Eye Irritation in Rabbits	Not assigned	Universal Bacteria Specialist	own	
	Study ID 17368-13. 16 pages				
870.2500	Kuhn, J. (2013) Acute Eye Irritation in Rabbits	Not assigned	Universal Bacteria Specialist	own	
	Study ID 17369-13. 11 pages				

Signature	Name and Title	Date
	Kevin R. Kutcel - Agent	11/25/2013

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Signature	Name and Title	Date
	Kevin R. Kutcel - Agent	11/25/2013

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 11/25/2013	EPA Reg No./File Symbol 87636-	Page 2 of 3
Applicant's/Registrant's Name & Address Universal Bacteria Specialist, PO Box 570324, Houston, TX 77257	Product Envirolyte	

Ingredient Hypochlorous Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	not assigned	Universal Bacteria Specialist	own	
830.1600	Description of Materials Used to Produce the Product	not assigned	Universal Bacteria Specialist	own	
830.1650	Description of Formulation Process	not assigned	Universal Bacteria Specialist	own	
830.1750	Discussion of the Formulation of Impurities	not assigned	Universal Bacteria Specialist	own	
830.1800	Enforcement Analytical Method	not assigned	Universal Bacteria Specialist	own	
830.1900	Submittal of Samples	not assigned	Universal Bacteria Specialist	own	

Signature	Name and Title	Date
K Kutcel	Kevin R. Kutcel - Agent	11/25/2013

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 11/25/2013	EPA Reg No./File Symbol 87636-	Page 2 of 3
Applicant's/Registrant's Name & Address Universal Bacteria Specialist, PO Box 570324, Houston, TX 77257	Product Envirolyte	

Ingredient Hypochlorous Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Universal Bacteria Specialist	own	
			Universal Bacteria Specialist	own	
			Universal Bacteria Specialist	own	
			Universal Bacteria Specialist	own	
			Universal Bacteria Specialist	own	
			Universal Bacteria Specialist	own	

Signature	Name and Title	Date
[signature]	Kevin R. Kutcel - Agent	11/25/2013

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DATA MATRIX

Date 11/25/2013	EPA Reg No./File Symbol 87636	Page 3 of 3
Applicant's/Registrant's Name & Address Universal Bacteria Specialist, PO Box 570324, Houston, TX 77257	Product Envirolyte	

Ingredient Hypochlorous Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6302	Color	not assigned	sBioMed LLC	own	
830.6303	Physical State	not assigned	sBioMed LLC	own	
830.6304	Odor	not assigned	sBioMed LLC	own	
830.6314	Oxidation / Reduction; chemical incompatibility	not assigned	sBioMed LLC	own	
830.6315	Flammability	not assigned	sBioMed LLC	own	
830.6316	Explodability	not assigned	sBioMed LLC	own	
830.6317	Storage Stability	not assigned	sBioMed LLC	own	
830.6319	Miscibility	not assigned	sBioMed LLC	own	
830.6320	Corrosion Characteristics	not assigned	sBioMed LLC	own	
830.6321	Dielectric Breakdown	not assigned	sBioMed LLC	own	
830.7000	pH	not assigned	sBioMed LLC	own	
830.7100	Viscosity	not assigned	sBioMed LLC	own	
830.7300	Density	not assigned	sBioMed LLC	own	

Signature	Name and Title	Date
K Kutcel	Kevin R. Kutcel / Agent	11/25/2013

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 11/25/2013	EPA Reg No./File Symbol 87636	Page 3 of 3
Applicant's/Registrant's Name & Address Universal Bacteria Specialist, PO Box 570324, Houston, TX 77257	Product Envirolyte	

Ingredient Hypochlorous Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	

Signature	Name and Title	Date
K J Kutcel	Kevin R. Kutcel / Agent	11/25/2013

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

A540 - New end use product.

- Must submit or reference Group A and B product chemistry, toxicity, and/or efficacy data for each proposed product.
- Data waivers may be requested. Chemistry data on the TGAI in addition to the EP is required if an unregistered source is used.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.1550	Product Identity & Composition	✓		
830.1600	Description of materials used to produce the product	✓		
830.1650	Description of formulation process	✓		
830.1670	Discussion on the formation of impurities	✓		
830.1700	Preliminary analysis	✓		
830.1750	Certified limits (158.345)	✓		
830.1800	Enforcement analytical method	✓		

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.6302	Color	✓		
830.6303	Physical State	✓		
830.6304	Odor	✓		
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓		
830.6315	Flammability	✓		
830.6316	Explodability	✓		
830.6317	Storage stability*	✓		
830.6319	Miscibility	✓		
830.6320	Corrosion Characteristics*	✓		
830.6321	Dielectric Breakdown Voltage	✓		
830.7000	pH	✓		
830.7050	UV/ Visible Absorption			
830.7100	Viscosity	✓		
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density	✓		
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required *May not be included with initial application

A540 – Acute Toxicity Requirements

New products must either:
1) supply the product specific acute toxicity 6 pack data (listed below),
2) provide a bridging rationale document or waiver request or,
3) use the cite all method of data compensation, if applicable. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
830.1100	Acute Oral (LD50)		✓		
830.1200	Acute Dermal (LD50)		✓		
830.1300	Acute Inhalation (LC50)		✓		
830.2400	Acute Eye Irritation		✓		
830.2500	Acute Dermal Irritation		✓		
830.2600	Dermal Sensitization		✓		

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 2, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-485380
EPA File Symbol or Registration Number: 87636-E
Product Name: ~~ANOLYTE~~ ENVIROLYTE
EPA Receipt Date: 27-Nov-2013
EPA Company Number: 87636
Company Name: UNIVERSAL BACTERIA SPECIALIST, INC.

GEORGE SANFORD
UNIVERSAL BACTERIA SPECIALIST, INC.
P.O. BOX 570324
HOUSTON, TX 77257

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code A540:
NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

cc: Kevin R. Kutcel, KRK Consulting LLC

Fee for Service

{944289W~

This package includes the following

- ◉ New Registration
- ○ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 32

Receipt No. S- 944289

EPA File Symbol/Reg. No. 87636-E

Pin-Punch Date: 11/27/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A540

Granted: A540

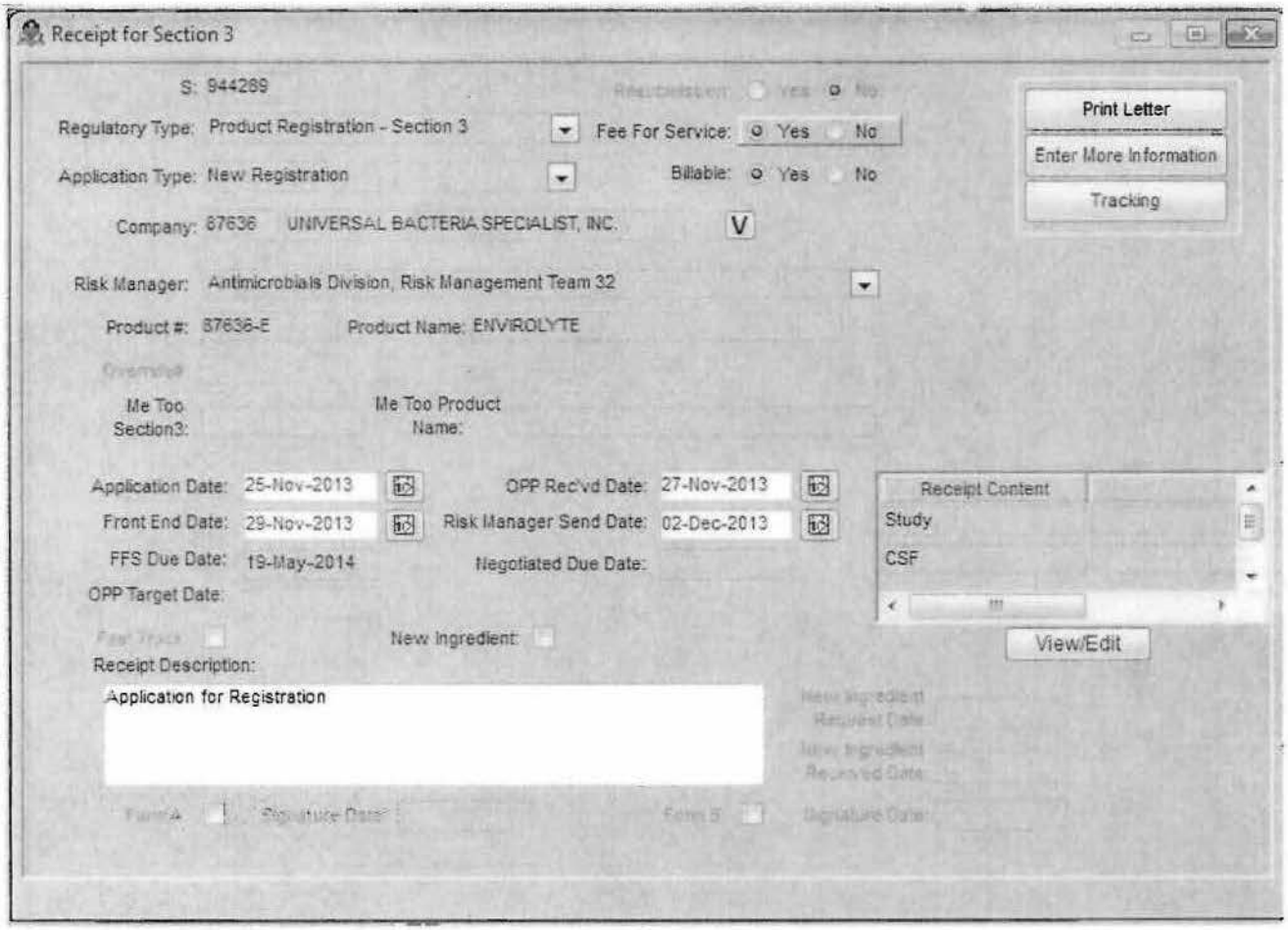
Amount Due: $ 4563

Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: [illegible] Date: 11/2013

Remarks:


Receipt for Section 3
S: 944289
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Company: 87636 UNIVERSAL BACTERIA SPECIALIST, INC.
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 32
Product #: 87636-E
Product Name: ENVIROLYTE
Me Too Section3:
Me Too Product Name:
Application Date: 25-Nov-2013
OPP Rec'vd Date: 27-Nov-2013
Front End Date: 29-Nov-2013
Risk Manager Send Date: 02-Dec-2013
FFS Due Date: 19-May-2014
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
New Ingredient:
View/Edit
Receipt Description:
Application for Registration

Online Payment

Step 3: Confirm Payment 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25D5IJVO
Agency Tracking ID: 74530246650
Transaction Date and Time: 11/15/2013 11:59 EST

Payment Summary

Account Holder Name: Universal Bacteria Spec
Payment Amount: $1,216.00
Account Type: Business Checking
Routing Number: [redacted]
Account Number: **********3797
Check Number: 2092

Payment Date: 11/18/2013
Decision Number:
Registration Number:
Company Name: Universal Bacteria Specia
Company Number: 87636
Action Code: A540

Commercial/financial information may be entitled to confidential treatment

KRK Consulting L.C
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
E-mail: kutcel@zoominternet.net

US EPA (REGFEE)
Office of Pesticide Programs
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

November 25, 2013

Subject: New Registration for Universal Bacteria Specialist (EPA No. 87636-)

Please accept the completed application for a new registration for the product, "Envirolyte", that contains the active ingredient, Hypochlorous Acid. Please note that this package includes an acute toxicity series (870 series) completed on this product which resulted in a category IV classification for studies. Therefore, the category IV rating is reflected on the attached label. The registrant, Universal Bacteria Specialist, already has a registration (87636-1) that contains 460 ppm hypochlorous acid. The label is identical to that registration, except the amount of hypochlorous acid is 1050 ppm.

Within this packet, the following information is included:

1. Receipt for payment (tracking number 74530246650) for a total of $1,216.00 corresponding to the action code "A540". Also attached is the completed application for the small business waiver along with supporting documentation.
2. Letter of authorization allowing KRK Consulting LLC to represent Universal Bacteria Specialist in all matters related to the U.S. EPA.
3. Application for the Registration for "Envirolyte" that includes:
    a. Five (5) copies of proposed EPA Label with CD that contains pdf of proposed label.
    b. Form 8570-1 Application Form
    c. Form 8570-34 Certification with Respect to Citation of Data
    d. Form 8570-4 Confidential Statement of Formula
    e. Form 8570-35 Data Matrix (6 pages)
    f. Three (3) copies of Product Chemistry, Subgroup A, 830 Series
    g. Three (3) copies of Product Chemistry, Subroup B, 830 Series.
    h. Three (3) copies of Storage Stability Study, Project WTC-13-004010
    i. Three (3) copies of Acute Oral Toxicity (UDP) in Rats. ID No. 17365-13
    j. Three (3) copies of Acute Dermal Toxicity in Rabbits. ID No. 17366-13
    k. Three (3) copies of Acute Inhalation Toxicity in Rats. ID No. 17367-13
    l. Three (3) copies of Acute Eye Irritation in Rabbits. ID No. 17368-13
    m. Three (3) copies of Acute Dermal Irritation in Rabbits. ID No. 17369-13
    n. Three (3) copies of Skin Sensitization in Guinea Pigs. ID No. 17370-13

Your cooperation in processing this application in an expedient manner is greatly appreciated. Please call me at 440-263-7305 if you should have any questions.

Best Regards,

Kevin R. Kutcel,
Agent for Universal Bacteria Specialist Inc.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060 Print Form

United States Environmental Protection Agency Washington, DC 20460

[X] Registration [ ] Amendment [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: Universal Bacteria Specialist / 87636-

2. EPA Product Manager: Demson Fuller

3. Proposed Classification: [X] None [ ] Restricted

4. Company/Product (Name): Universal Bacteria Specialist /Envirolyte

PM#

5. Name and Address of Applicant (Include ZIP Code)
Universal Bacteria Specialist
PO Box 570324
Houston, TX 77257

[ ] Check if this is a new address

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[X] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Please see cover letter.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No		[ ] Yes [X] No		[ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	

3. Location of Net Contents Information: [X] Label [ ] Container

4. Size(s) Retail Container

5. Location of Label Directions: [ ] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [X] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name	Title	Telephone No. (Include Area Code)
Kevin R. Kutcel	Agent	440-263-7305

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature

3. Title: Agent

4. Typed Name: Kevin R. Kutcel

5. Date: November 25, 2013

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Please read instructions on reverse before ~~xloting form.~~ Form Appro OMB No. 2070-0060

Print Form

United States
Environmental Protection Agency
Washington, DC 20460

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Universal Bacteria Specialist / 87636-	Demson Fuller	[X] None [ ] Restricted
4. Company/Product (Name) Universal Bacteria Specialist / Anolyte	PM#	

5. Name and Address of Applicant *(Include ZIP Code)*
Universal Bacteria Specialist
PO Box 570324
Houston, TX 77257
[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[X] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Please see cover letter.

Deficiency
wrong
product
name

Sectio

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Sol
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wt

3. Location of Net Contents Information
[X] Label [ ] Container

4. Size(s) Retail Container
1,55,275,330,6 ot

6. Manner in Which Label is Affixed to Product
[ ] Lithograph
[X] Paper glued
[ ] Stenciled

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Kevin R. Kutcel	Agent	440-263-7305

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
[signature]	Agent
4. Typed Name Kevin R. Kutcel	**5. Date** November 25, 2013

UNIVERSAL BACTERIA SPECIALIST, INC.

May 18, 2010

U.S. Environmental Protection Agency
Office of Pesticide Programs (COADR)
Document Processing Desk (7504P)
One Potomac Yard – Room S4900
2777 S. Crystal Drive
Arlington, VA 22202

RE: Authorization for Representation / Agent Status

Pursuant to 40 CFR 152.50 (b)(3), we hereby designate Kevin Kutcel of KRK Consulting LLC as an Authorized Agent to act in behalf of Universal Bacteria Specialist, Inc. with respect to all registration matters that may come before the Agency. The address of record for all matters related to FIFRA will be:

Universal Bacteria Specialist, Inc.
c/o Kevin Kutcel
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256

Contact: Kevin Kutcel – Tel. 440-263-7305

This authorization will remain valid until further notice is given by either Universal Bacteria Specialist, Inc. or KRK Consulting LLC.

If you have any questions, please contact KRK Consulting LLC at 440-263-7305

Sincerely

Mr. Chuck Ludwig
Universal Bacteria Specialist, Inc.

Cc: Kevin Kutcel – KRK Consulting LLC

P.O. Box 570324 – Houston, TX 77257
281/342-9555 Corporate Office – 281/344-9709 Fax

Form Approved OMB Nos. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Universal Bacterial Specialist, PO Box 570324, Houston, TX 77257	EPA Registration Number/File Symbol 87636-
Active Ingredient(s) and/or representative test compound(s) Hypochlorous Acid	Date November 25, 2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Bactericide	Product Name Envirolyte

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (i... under the ... m a ...ust be

SECTION II: GENERAL OI

Corrected

[Required if using the cite-all method or when using the cite-all option under the selectiv...

☑ I hereby offer and agree to pay compensation, to other persons, with regard to th...

SECTION III: CERTIFI(

I certify that this application for registration, this form for reregistration, or this D... application for registration, the form for reregistration, or the Data-Call-In response. In adc... indicated in Section I, this application is supported by all data in the Agency's files that (1)... substantially similar product, or one or more of the ingredients in this product; and (2) is a t... requirements in effect on the date of approval of this application if the application sought th... uses.

I certify that for each exclusive use study cited in support of this registration or re... the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration tha... submitter; (b) I have obtained the permission of the original data submitter to use the study i... compensation have expired for the study; (d) the study is in the public literature; or (e) I have ...ounted in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA, and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	11/25/13	Kevin R. Kutcel - Agent

Form Approved OMB Nos. 20[illegible]0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Universal Bacterial Specialist, PO Box 570324, Houston, TX 77257	87636-
Active Ingredient(s) and/or representative test compound(s) Hypochlorous Acid	Date November 25, 2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Bactericide	Product Name Anolyte

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this f[illegible] of compensation (the Data Matrix form should be used for this purpose).

SEC[illegible] Deficiency [illegible])

☐ I am using the cite-all method of support, [illegible]ive method of support (or cite-all option a list of companies sent offers of compens[illegible]ethod), and have included with this form a should be used for this purpose). [illegible] requirements (the Data Matrix form must be

wrong product name

[Required if using the cite-all method or when using [illegible] data requirements]

☑ I hereby offer and agree to pay compensation [illegible] the extent required by FIFRA.

I certify that this application for registration, t[illegible]d by all data submitted or cited in the application for registration, the form for reregistration, or [illegible] all option under the selective method is indicated in Section I, this application is supported by all [illegible] properties or effects of this product or an identical or substantially similar product, or one or more of the ingrec[illegible] and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this app[illegible] if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
[signature]	11/25/13	Kevin R. Kutcel - Agent

32

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 11/27/13

Experts In-Processing Signature: MP Date 12/3/13 Fee Paid: Yes ✓

Division management contacted on issues No_______ Yes_______ Date_______

EPA Reg. Number: 87636-E	EPA Receipt Date: 11/27/13					
	Items for Review			**Yes**	**No**	**N/A***
1	**Application Form** (EPA Form 8570-1) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A) *Active ingredient and water*	**yes**	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	**yes** X	**no**			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**			X		
7	**Is the data package consistent with PR Notice 86-5**			X		
8	**Notice of Filing included with petitions**					X

9	**If applicable for conventional applications, <u>reduced risk rationale</u>**			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments: 5 studies passed 11-3 review Pass 49 & 641.

Active ingredient and water only, no inerts to review.

12/12/13 - An e-mail was sent to the registrant regarding the application form and the Certification form which had a deficiency.

- Received corrected forms.

TO

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Jackson, Tracy

From: Jackson, Tracy
Sent: Tuesday, December 17, 2013 8:48 AM
To: 'kutcel@zoominternet.net'
Subject: Application Deficiency (87636-E)

Dear Mr. Kutcel,

I am contacting you regarding your submission in support of **Envirolyte (87636-E)**. The application form (8570-1) and the Certification with Respect to Citation of Data form (8570-34) have Anolyte as the product name. The other forms have Envirolyte as the product name. Please clarify.

There are studies that are associated with this application that are currently under review. If there are any deficiencies you will be contacted at a later date.

Thank You

Tracy Jackson
EPA Contractor
703-308-7227
2777 S. Crystal Drive
Arlington, VA 22202

IB

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

Thursday, February 06, 2014

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 87636-E
DP Barcode: D417070
Product Name: EnviroLyte

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: Demson Fuller, PM 32
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: Universal Bacteria Specialist, Inc.

FORMULATION FROM LABEL:

PC Code	Active Ingredient(s):	% by wt.
129054	Hypochlorous Acid	0.105
	Other Ingredient(s):	99.895
	Total:	100.000

I BACKGROUND: Universal Bacteria Specialist, Inc., has submitted a complete set of six acute toxicity studies to support the data requirements of their pending registration, "Envirolyte". Stillmeadow, Inc., conducted these studies.

This hypochlorous acid product is unique in that it is produced "through the electrolysis of sodium chloride in water". The product label states that this product is to be used for fracturing and water flood injection wells.

There is a discrepancy in that the product is named "Envirolyte"; but, the test material is called "Envirolyte O&G". The Chemistry and Toxicology Team (CTT) contacted Universal Bacteria Specialist's consultant, Kevin Kutcel, concerning this matter via email. Mr. Kutcel informed CTT that "'Envirolyte O&G' is identical to 'Envirolyte'."

II RECOMMENDATIONS:

1. Each of the six studies is acceptable.

The acute toxicity profile for File Symbol 87636-E is currently:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	49264104	IV	Acceptable
Acute Dermal Toxicity	49264105	IV	Acceptable
Acute Inhalation Toxicity	49264106	IV	Acceptable
Primary Eye Irritation	49264107	IV	Acceptable
Primary Skin Irritation	49264108	IV	Acceptable
Dermal Sensitization	49264109	Nonsensitizer	Acceptable

III LABELING:

1. The Signal Word, "CAUTION", is optional.

2. Due to the acute toxicity profile of this product, no Precautionary Statements or First Aid statements are required for 87636-E.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

Up and Down Procedure

Product Manager: 32 **Reviewer:** I. Blackwell

MRID No.: 49264104 **Study Completion Date:** 8/2/2013

Lab Study No.: 17365-13

Testing Laboratory: Stillmeadow, Inc.

Authors: Janice O. Kuhn, PhD, DABT

Quality Assurance (40 CFR §160.12): Included

Test Material: Envirolyte O&G ; "clear liquid"

Species: Sprague-Dawley albino rat

Weight: 184-200 g **Age:** 10 weeks

Source: Texas Animal Specialties

Conclusion:

1. LD_{50} (mg/kg): **Males=** Not tested

Females> 5,000 mg/kg b.w.

Combined= Not tested

2. The estimated LD_{50} is greater than 5,000 mg/kg of body weight.

3. Tox. Category: IV **Classification:** Acceptable

Procedure (Deviations from §81-1): None

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5,000	---	0/3	---

Observations: The lab noted no clinical signs of toxicity.

Gross Necropsy: There were no observable abnormalities.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: 32 **Reviewer:** I. Blackwell
MRID No.: 49264105 **Study Completion Date:**
Lab Study No.:

Testing Laboratory: Stillmeadow, Inc.
Author: Janice O. Kuhn, PhD, DABT
Quality Assurance (40 CFR §160.12): Included

Test Material: Envirolyte O&G ; "clear liquid"

Species: New Zealand White albino rabbit
Weight: Males= 2.4-3.1 kg **Age:** 17 weeks
Females= 3.1-3.3 kg
Source: Veterinary Clinical Resources

Summary:

1. **LD_{50} (mg/kg):**
   Males > 5,050 mg/kg b.w.
   Females > 5,050 mg/kg b.w.
   Combined > 5,050 mg/kg b.w.
2. **The estimated LD_{50} is greater than 5,050 mg/kg of body weight.**
3. **Tox. Category:** IV **Classification:** Acceptable

Procedure (Deviation From §81-2): None

Results:

Reported Mortality

DOSAGE (mg/kg)	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
5,050 mg/kg	0/5	0/5	0/10

Observations: Animals were normal at each observation.

Gross Necropsy Findings: The lab reported no observable abnormalities.

DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-3, 870.1300)

Product Manager: 32 **Reviewer:** I. Blackwell
MRID No.: 49264106 **Study Completion Date:** 8/13/2013
Lab Study No.: 17367-13

Testing Laboratory: Stillmeadow, Inc.
Author: Andrew Doig, M.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Envirolyte O&G ; "clear liquid"
Concentration: 2.12 mg/L

Species: Sprague-Dawley rat
Weight: Males= 291-343 g Females= 193-208 g
Age: 11 weeks
Source: Texas Animal Specialties

Summary:

1. **LC_{50} (mg/L)** **Males** > 2.12 mg/L
   Females > 2.12 mg/L
   Combined > 2.12 mg/L
2. **The estimated LC_{50} is greater than 2.12 mg/L of air.**
3. **MMAD:** 1.5 **µm**
4. **Toxicity Category:** IV **Classification:**

Procedure (Deviation From §81-3): None

Results:

Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
2.12 mg/L	0/5	0/5	0/10

Chamber Atmosphere			
Dose Level	MMAD	GSD	Particles < 3.7 µm
2.12 mg/L	1.5 µm	2.8 µm	83.33%

Chamber Environment	
Chamber Volume	500 L
Airflow	218 lpm
Temperature	21.2-23.5° C
Relative Humidity	68-83%

Clinical Observations: The subjects appear normal at each observation.

Gross Necropsy Findings: The lab reported no observable abnormalities.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 32 **Reviewer:** I. Blackwell
MRID No.: 49264107 **Study Completion Date:** 8/2/2013
Lab Study No.: 17368-13

Testing Laboratory: Stillmeadow, Inc.
Author(s): Janice O. Kuhn, PhD, DABT

Quality Assurance (40 CFR §160.12): Included

Test Material: Envirolyte O&G ; "clear liquid"
Dosage: 0.1 mL

Species: New Zealand White albino rabbit **Sex:** 2 males + 1 female
Weight: 2.120-2.270 kg **Age:** 10 weeks
Source: Veterinary Clinical Resources

Summary:

1. **Toxicity Category:** IV

2. **Classification:** Acceptable

Procedure (Deviations From §81-4): None

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	0/3	0/3	0/3	---	---	---	---
Iritis	0/3	0/3	0/3	0/3	---	---	---	---
Conjunctivae								
Redness	0/3	0/3	0/3	0/3	---	---	---	---
Chemosis	0/3	0/3	0/3	0/3	---	---	---	---
Discharge	0/3	0/3	0/3	0/3	---	---	---	---

- - - = no observations at this point

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 32
MRID No.: 49264108

Reviewer: I. Blackwell
Study Completion Date: 8/2/2013
Lab Study No.: 17369-13

Testing Laboratory: Stillmeadow, Inc.
Study Director: Janice O. Kuhn, PhD, DABT

Quality Assurance (40 CFR §160.12): Included

Test Material: Envirolyte O&G ; "clear liquid"
Dosage: 0.5 mL

Species: New Zealand White albino rabbit
Weight: 2.6-2.758 kg **Age:** 11 weeks
Source: Veterinary Clinical Resources

Summary:

1. **Toxicity Category:** IV

2. **Classification:** Acceptable

Procedure (Deviations From §81-5): None

Results: No irritation was observed one hour after treatment. Twenty-four and forty-eight hours after treatment, 3/3 subjects had very slight erythema and edema. Seventy-two hours after treatment, 2/3 displayed very slight erythema and 0/3 displayed edema.

Special Comments: None

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: 32 **Reviewer:** I. Blackwell
MRID No.: 49264108 **Study Completion Date:** 8/20/2013
Lab Study No.: 17370-13

Testing Laboratory: Stillmeadow, Inc.
Author: Janice O. Kuhn, PhD, DABT

Quality Assurance (40 CFR §160.12): Included

Test Material: Envirolyte O&G ; "clear liquid"
Positive Control Material: Alpha-hexylcinnamaldehyde, 85%

Species: Hartley Albino guinea pig
Weight: 342-482 g **Age:** 6 weeks
Source: Charles River, Hdq

Method: Modified Buehler Method

Summary:

1. **This Product is not a dermal sensitizer.**

2. **Classification:** Acceptable

Procedure (Deviation From §81-6):

Procedure: The test subjects were treated with 0.4 mL of undiluted (100%) test substance (6 hrs contact) once weekly for three weeks. After a two week rest period, the subjects were challenged with undiluted test material.

Results: The lab reported that there was no irritation (erythema or edema) during induction or after challenge.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 04, 2013

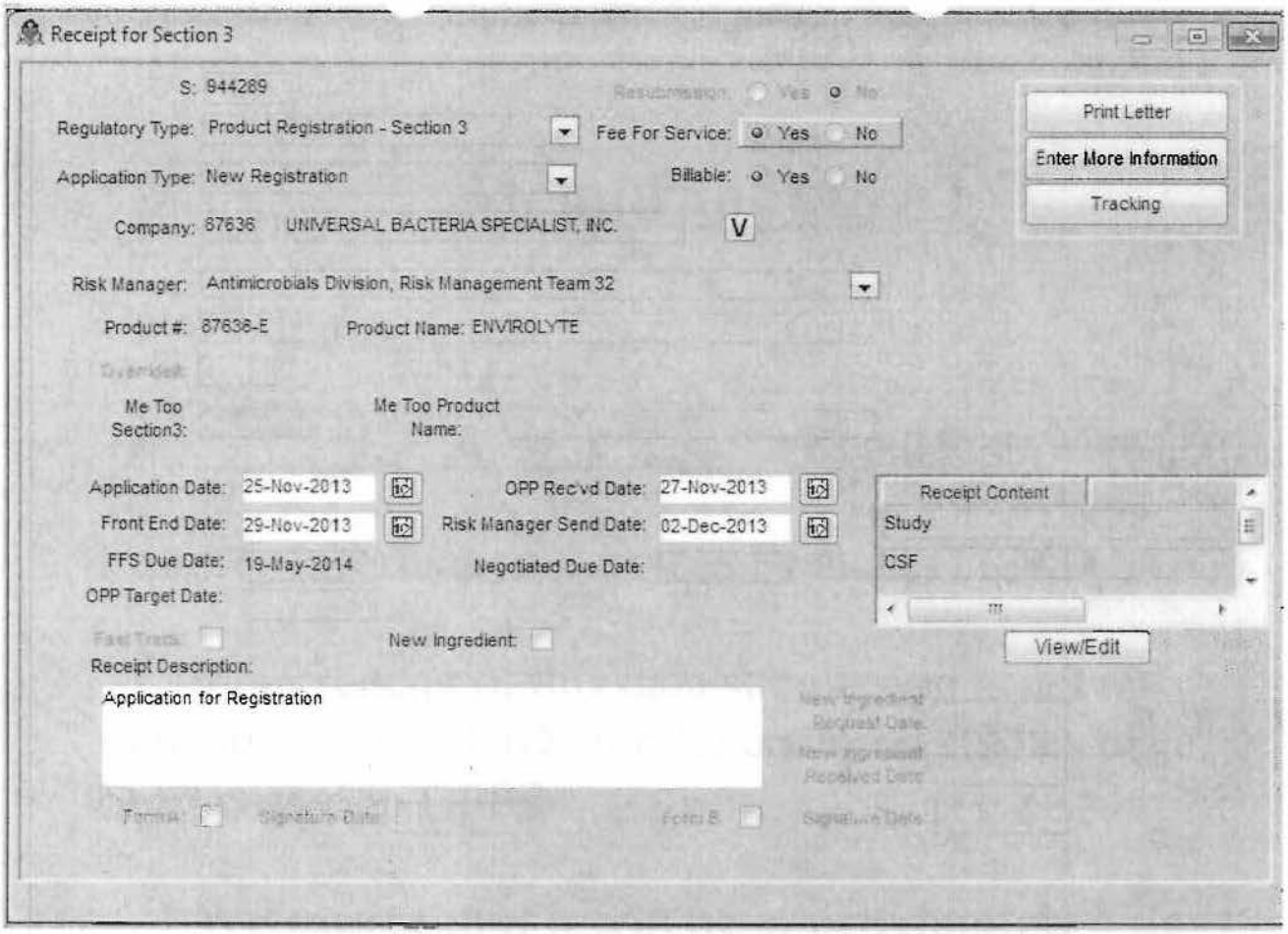
OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

UNIVERSAL BACTERIA SPECIALIST, INC.
1117 FM 359, STE 140
RICHMOND, TX 77406

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 27-NOV-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.


Receipt for Section 3
S: 944289
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Company: 87636 UNIVERSAL BACTERIA SPECIALIST, INC.
Risk Manager: Antimicrobials Division, Risk Management Team 32
Product #: 87636-E
Product Name: ENVIROLYTE
Overridden:
Me Too Section3:
Me Too Product Name:
Application Date: 25-Nov-2013
OPP Rec'vd Date: 27-Nov-2013
Front End Date: 29-Nov-2013
Risk Manager Send Date: 02-Dec-2013
FFS Due Date: 19-May-2014
Negotiated Due Date:
OPP Target Date:
Fast Track:
New Ingredient:
Receipt Description:
Application for Registration
Form A:
Signature Date:
Form B:
Signature Date:
Print Letter
Enter More Information
Tracking
Receipt Content
Study
CSF
View/Edit

Memorandum

Date: 12 / 18 / 13

To: PM 32, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 3/11/2014	EPA Reg No./File Symbol 87636-E	Page 1 of 4
Applicant's/Registrant's Name & Address Universal Bacteria Specialist, PO Box 570324, Houston, TX 77257	Product Envirolyte	

Ingredient Hypochlorous Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2600	Kuhn, J. (2004) Skin Sensitization Study in Guinea Pigs:	49264109	Universal Bacteria Specialist	own	
	Study ID. 17370-13 16 pages				
870.1100	Kuhn, J. (2013) Acute Oral Toxicity Study (UDP) in Rats	49264104	Universal Bacteria Specialist	own	
	Study ID 17365-13. 10 pages				
870.1200	Kuhn, J. (2013) Acute Dermal Toxicity Study in Rabbits	49264105	Universal Bacteria Specialist	own	
	Study ID 17366-13. 11 pages				
870.1300	Kuhn, J. (2013) Acute Inhalation Toxicity Study in Rats	49264106	Universal Bacteria Specialist	own	
	Study ID 17367-13. 17 pages				
870.2400	Kuhn, J. (2013) Acute Eye Irritation in Rabbits	49264107	Universal Bacteria Specialist	own	
	Study ID 17368-13. 16 pages				
870.2500	Kuhn, J. (2013) Acute Eye Irritation in Rabbits	49264108	Universal Bacteria Specialist	own	
	Study ID 17369-13. 11 pages				

Signature	Name and Title	Date
	Kevin R. Kutcel - Agent	03/11/2014

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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DATA MATRIX

Date 3/11/2014	EPA Reg No./File Symbol 87636-E	Page 1 of 4
Applicant's/Registrant's Name & Address Universal Bacteria Specialist, PO Box 570324, Houston, TX 77257	Product Envirolyte	

Ingredient Hypochlorous Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Universal Bacteria Specialist	own	
			Universal Bacteria Specialist	own	
			Universal Bacteria Specialist	own	
			Universal Bacteria Specialist	own	
			Universal Bacteria Specialist	own	
			Universal Bacteria Specialist	own	

Signature	Name and Title	Date
[signature]	Kevin R. Kutcel - Agent	03/11/2014

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 3/11/2014	EPA Reg No./File Symbol 87636-E	Page 2 of 4
Applicant's/Registrant's Name & Address Universal Bacteria Specialist, PO Box 570324, Houston, TX 77257	Product Envirolyte	

Ingredient Hypochlorous Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	49264101	Universal Bacteria Specialist	own	
830.1600	Description of Materials Used to Produce the Product	49264101	Universal Bacteria Specialist	own	
830.1650	Description of Formulation Process	49264101	Universal Bacteria Specialist	own	
830.1750	Discussion of the Formulation of Impurities	49264101	Universal Bacteria Specialist	own	
830.1800	Enforcement Analytical Method	49264101	Universal Bacteria Specialist	own	
830.1900	Submittal of Samples	49264101	Universal Bacteria Specialist	own	

Signature	Name and Title	Date
	Kevin R. Kutcel - Agent	03/11/2014

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DATA MATRIX

Date 3/11/2014	EPA Reg No./File Symbol 87636-E	Page 2 of 4
Applicant's/Registrant's Name & Address Universal Bacteria Specialist, PO Box 570324, Houston, TX 77257	Product Envirolyte	

Ingredient Hypochlorous Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]	[redacted]	[redacted]	Universal Bacteria Specialist	own	
			Universal Bacteria Specialist	own	
			Universal Bacteria Specialist	own	
			Universal Bacteria Specialist	own	
			Universal Bacteria Specialist	own	
			Universal Bacteria Specialist	own	

Signature	Name and Title	Date
[signature]	Kevin R. Kutcel - Agent	03/11/2014

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DATA MATRIX

Date 3/11/2014	EPA Reg No./File Symbol 87636-E	Page 3 of 4
Applicant's/Registrant's Name & Address Universal Bacteria Specialist, PO Box 570324, Houston, TX 77257	Product Envirolyte	

Ingredient Hypochlorous Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6302	Color	49264102	sBioMed LLC	own	
830.6303	Physical State	49264102	sBioMed LLC	own	
830.6304	Odor	49264102	sBioMed LLC	own	
830.6314	Oxidation / Reduction; chemical incompatibility	49264102	sBioMed LLC	own	
830.6315	Flammability	49264102	sBioMed LLC	own	
830.6316	Explodability	49264102	sBioMed LLC	own	
830.6317	Storage Stability	49264102	sBioMed LLC	own	
830.6319	Miscibility	49264102	sBioMed LLC	own	
830.6320	Corrosion Characteristics	49264102	sBioMed LLC	own	
830.6321	Dielectric Breakdown	49264102	sBioMed LLC	own	
830.7000	pH	49264102	sBioMed LLC	own	
830.7100	Viscosity	49264102	sBioMed LLC	own	
830.7300	Density	49264102	sBioMed LLC	own	

Signature	Name and Title	Date
	Kevin R. Kutcel / Agent	03/11/2014

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DATA MATRIX

Date 3/11/2014	EPA Reg No./File Symbol 87636-E	Page 3 of 4
Applicant's/Registrant's Name & Address Universal Bacteria Specialist, PO Box 570324, Houston, TX 77257	Product Envirolyte	

Ingredient Hypochlorous Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
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			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	
			sBioMed LLC	own	

Signature	Name and Title	Date
	Kevin R. Kutcel / Agent	03/11/2014

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DATA MATRIX

Date 3/11/2014	EPA Reg No./File Symbol 87636-E	Page 4 of 4
Applicant's/Registrant's Name & Address Universal Bacteria Specialist, PO Box 570324, Houston, TX 77257	Product Envirolyte	

Ingredient Hypochlorous Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1035	Mysid Acute Toxicity Test	47642402	Halliburton Energy Services	pay	
850.1055	Bivalve Acute Toxicity Test (Embryo Larval)	48788602	Thatcher Company	pay	
850.1075	Fish Acute Toxicity, Freshwater and Marine	7401	Chlorine Institute	old	

Signature	Name and Title	Date
	Kevin R. Kutcel - Agent	03/11/2014

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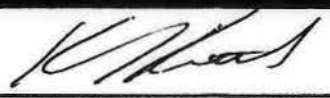
DATA MATRIX

Date 3/11/2014	EPA Reg No./File Symbol 87636-E	Page 4 of 4
Applicant's/Registrant's Name & Address Universal Bacteria Specialist, PO Box 570324, Houston, TX 77257	Product Envirolyte	

Ingredient Hypochlorous Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Hallibuton Energy Services	pay	
			Thatcher Company	pay	
			Chlorine Institute	old	

Signature	Name and Title	Date
	Kevin R. Kutcel - Agent	03/11/2014

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
E-mail: kevinkutcel@gmail.com

January 29, 2014

Mr. Demson Fuller (MS- 7510P)
US Environmental Protection Agency
Office of Pesticide Programs
Antimicrobial Division (S-8824)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Envirolyte (Reg. No. 87636-E)

Dear Mr. Fuller,

I am responding to our phone conversation on January 7, 2014 when we discussed the potential requirement of Reg. No. 87636-E requiring additional data to support the proposed enduse for oil and gas applications. The reason for this potential requirement is the proposed registration contains 0.105% hypochlorous acid versus 0.0460% for current hypochlorous acid registrations approved for the same enduse. I would propose that the data used to support oil and gas applications for sodium hypochlorite be bridged to support the same application for hypochlorous acid. Sodium hypochlorite is already approved for oil and gas applications (Reg. No. 40153-1) containing 12.5% sodium hypochlorite. In this label, the amount of chlorine used for both the initial and maintenance treatments in drilling and fracking applications is 10-1,000 ppm chlorine depending upon the level of contamination. In our proposed registration (Reg. No. 87636-E), the amount of FAC proposed is 2.5-500 ppm. There are several reasons why this proposal is scientifically valid and reasonable.

1. Chemistry of Sodium Hypochlorite and Hypochlorous Acid – Hypochlorous acid is the weak acid of sodium hypochlorite. In other words, sodium hypochlorite is the sodium salt of hypochlorous acid. Both products are formed through the dissolution of chlorine in water. Both products are oxidizers and undergo identical reactions in their biochemical activity. The separation of the products is dependent upon pH and the products often exist in a chemical equilibrium. In addition, both products rapidly degrade into non-toxic compounds when exposed to sunlight.

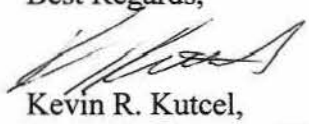
In such situations, the US EPA has a long history of bridging data between compounds that are in the same chemical family such as the weak acids of salts and vica versa. In this case, the sodium hypochorite is the sodium salt which forms at the higher pH when the chlorine gas is dissolved in sodium hydroxide versus water for the hypochlorous acid. It is my understanding that the US EPA has already agreed that all generic data for sodium hypochlorite be bridged for hypochlorous acid due to their chemical similarities. This proposal is asking for the same consideration for this particular enduse.

2. Regulatory Status of Sodium Hypochlorite – In February, 1986 the US EPA issued a registration standard stating that no additional scientific data would be necessary to register sodium hypochlorite products between 5.25% to 12.5% as long as the sole diluent is water. In addition, the environmental fate data requirements for the hypochlorite salts were satisfied by the document, Ambient Water Quality Criteria for Chlorine, by J. Tobler, US EPA, June 1981 and the citation of MRID Nos. 40911802, 05011199 and 05021388 as stated on page 30 of the RED for sodium hypochlorite. The ecological effects data has also been satisfied by the citation of MRID Nos. 7276, 7403, 7275, 7205, 7278, 7404, 8109, 7401, 40911802, 8191, 7400, 7279, 7402, 19313, as stated on page 28 of the sodium hypochlorite RED.

3. Actual Exposure of Chlorine to Environment – the biological activity of both sodium hypochlorite and hypochlorous acid is dependent upon the activity of FAC (free available chlorine) as released by the respective compounds. And any environmental concerns should be on the exposure of chlorine in the environment and not hypochlorous acid as it quickly degrades to chlorine gas and water. Therefore, it is more accurate to focus upon the amount of FAC being utilized than the actual compounds. The sodium hypochlorite registration (Reg. No. 40153-1) is approved for use in oil and gas applications between 10-1,000 ppm chlorine. This is double the proposed rate on the subject registration (Reg. No. 87636-E) which states 2.5-500 ppm FAC depending upon the application. Also, please note that though the proposed registration contains a higher level of hypochlorous acid (0.105%) than currently approved labels containing 460 ppm, the amount of actual chlorine being utilized in the application is identical to Reg.No. 87636-1. Therefore, there is no greater exposure of chlorine to the environment between Reg. no. 87636-1 and 87636-E.

I believe the above points are reasonable that the proposed label, Reg. No. 87636-E, be allowed to bridge all data from sodium hypochlorite for the oil and gas application as stated on the label. Your cooperation in this matter is greatly appreciated. Please contact me at 440-263-7305 or kevinkutcel@gmail.com if you have any questions.

Best Regards,



Kevin R. Kutcel,
Agent for Universal Bacteria Specialist

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

May 8, 2014

DP BARCODE:	417073
MRID:	49264100, 49264101, 49264102, 49264103 and 49377300, 49377301, and 49377302
SUBJECT:	Envirolyte
REG. NO.:	87636-E
DOCUMENT TYPE:	Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
129054	7790-92-3	Hypochlorous Acid

TEST LAB:	Intertek Technology Center
SUBMITTER:	KRK Consulting LLC
GUIDELINE:	Group A and B Product Chemistry
ORGANIZATION:	AD\PSB\CTT
REVIEWER:	Lynette T. Umez-Eronini
APPROVED BY:	Karen P. Hicks
APPROVED DATE:	May 8, 2014
COMMENT:	This product is for non-food use.

L.T.U-E.
5/14/2014

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

May 8, 2014

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 87636-E
Product Name: Envirolyte
DP Barcode: 417073

FROM: Lynette T. Umez-Eronini, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Demson Fuller PM #32/Wanda Henson
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Universal Bacteria Specialist, Inc.

CODE: A540 New Product; Non-Fast Track;

DATE DUE: May 19, 2014

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Hypochlorous Acid	0.105
Other Ingredient(s):	99.895
Total:	100.000

BACKGROUND:

The consultant, KRK Consulting LLC, on behalf of the registrant, Universal Bacteria Specialist, Inc., has submitted an application for registration of an integrated end-use product called Envirolyte. This product is an antimicrobial agent that is used in water treatment for oil and gas applications. The product is for non-food use.

The product chemist reviewed the following documents:

1. Cover letter from the registrant to EPA, 11/25/2013.
2. Proposed EPA label, pin-punched 11/27/2013.
3. Form 8570-1 Application Form, 11/25/2013
4. Form 8570-34 Certification with Respect to Citation of Data, 11/25/2013.
5. Form 8570-4 Basic Confidential Statement of Formula (CSF), 11/25/2013.
6. 8570-34 (Certification with Respect to Citation of Data), January 2, 2014.
7. Form 8570-35 (Data Matrix), 11/25/2013, 6p.
8.

MRID	Citation	Receipt Date
49264100	Universal Bacteria Specialist, Inc. (2013) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Envirolyte. Transmittal of 9 Studies.	27-Nov-2013
49264101	Kutcel, K. (2013) Product Chemistry, Subgroup A (Envirolyte). Unpublished study prepared by Universal Bacteria Specialist, Inc. 25p.	27-Nov-2013
49264102	Kutcel, K. (2013) Product Chemistry, Subgroup B (Envirolyte). Unpublished study prepared by Universal Bacteria Specialist, Inc. 5p.	27-Nov-2013
49264103	Kilbane, J. (2013) Product Chemistry: Storage Stability (Envirolyte). Project Number: WTC/13/004010. 6p.	27-Nov-2013

The registrant sent additional documents to clear deficiencies that were cited by the product chemist in a technical screen review. The product chemist reviewed the following documents:

1.

49377300	Cover letter, May 2, 2014 same as transmittal letter. Universal Bacteria Specialist, Inc. (2014) Submission of Product Chemistry Data in Support of the Application for Registration of Envirolyte. Transmittal of 2 Studies.	07-May-2014
49377301	Kilbane, J. (2014) Product Chemistry: Storage Stability: Corrosion Characteristics: (Envirolyte). Project Number: WTC/13/004010. Unpublished study prepared by Intertek Technology Center. 4p.	07-May-2014
49377302	Kutcel, K. (2014) Product Chemistry: Description of Production Process: Description of Formulation Process: Preliminary Analysis: Enforcement Analytical Method: (Envirolyte). Unpublished study prepared by Universal Bacteria Specialist. 11p.	07-May-2014

FINDINGS:

1. The nominal concentration of the active ingredient on the Basic CSF is consistent with the label.
2. All ingredients in this formulation are approved for use in pesticide formulations.
3. Certified limits of all the ingredients are within the EPA Standard Certified Limits.
4. The deficiencies in Group A Product Chemistry data requirements: 830.1620 Description of Production Process, 830.1650 Discussion of Formulation Process, and 830.1700 Enforcement Analytical Method are cleared in MRID 49377302, which replaces the said requirements that are cited in MRID 49246401.
5. Group A product chemistry data requirements applicable to end-use products have been met (see MRID 49246401 and 49377302 and Table A below).
6. The deficiencies in Group B Product Chemistry data requirements: 830.6317 Storage Stability and 830.6320 Corrosion Characteristics are cleared in MRID 49377301, which replaces the said requirements that are cited in MRID 49246402 and 42246403.
7. Group B product chemistry data requirements applicable to end-use products have been met (see MRID 49264102, 49377301 and Table B below). Note: MRID 42246403 is unacceptable.

RECOMMENDATION:

1. It is suggested the actual value of the product viscosity would be reported on EPA Form 8570-36 (Summary of the Physical/Chemical Properties).

CONCLUSION:

The Basic CSF, 11/25/2013 is acceptable. Group A and Group B Product Chemistry data requirements have been met.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system — Yes [ ] No [X]
- Are all TGAIs used registered? — Yes [ ] No [X]
- Integrated formulation system — Yes [X] No [ ]
- If "ME-TOO," specify EPA Reg. No. of existing product:

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §180.940 and §180.950.

Yes [ ] No [X]

c. Physical state of product: Liquid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient	NC(%)	LCL(%)	UCL(%)
Hypochlorous acid	0.105	.094	.1155

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?

Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [ ] No [ ]

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	49264101
830.1600 Description of Materials	A	49264101
830.1620 Production Process[2]	A	49377302
830.1650 Formulation Process[3]	A	49377302
830.1670 Formation of Impurities[4]	A	49264101
830.1700 Preliminary Analysis[5]	A	49377302
830.1750 Certified Limits[6]	A	49264101
830.1800 Enforcement Analytical Method[7]	A	49377302
830.1900 Submittal of Samples	NA	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NA		
830.6303 Physical State	A	Liquid	EPA Form 8570-36 in 49264102
830.6304 Odor	N/A		
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA		EPA Form 8570-36 in 49264102
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	Not applicable, product has no oxidizing or reducing agents.	
830.6315 Flammability/ Flame Extension	A	Not applicable, product is water based.	EPA Form 8570-36 in 49264102
830.6316 Explodability	A	Not applicable, product is aqueous and not considered explosive.	EPA Form 8570-36 in 49264102
830.6317 Storage Stability	A	Stable for 30 days.	49377301
830.6319 Miscibility[1]	A	Not applicable, product is not an emulsifiable concentrate.	EPA Form 8570-36 in 49264102
830.6320 Corrosion Characteristics	G	Not corrosive.	49377301
830.6321 Dielectric Breakdown Voltage	A	Not applicable, product is not intended for use around electrical equipment.	EPA Form 8570-36 in 49264102
830.7000 pH[2]	A	6.5	EPA Form 8570-36 in 49264102
830.7050 UV/Visible Absorption	NA		
830.7100 Viscosity	A	Same as water (20 C).	EPA Form 8570-36 in 49264102
830.7200 Melting Point/Melting Range	NA		

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7220 Boiling Point/Boiling Range	NA		
830.7300 Density/Relative Density/Bulk Density	A	8.34 lbs/gal or 1.004 g/ml at 20C.	EPA Form 8570-36 in 49264102
830.7370 Dissociation Constants in Water	NA		
830.7550/830.7560/830.7570 Partition Coefficient	NA		
830.7840/830.7860 Water Solubility	NA		
830.7950 Vapor Pressure	NA		

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 09, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

KRK CONSULTING LLC
UNIVERSAL BACTERIA SPECIALIST, INC.
5807 CHURCHILL WAY
MEDINA, OH 44256

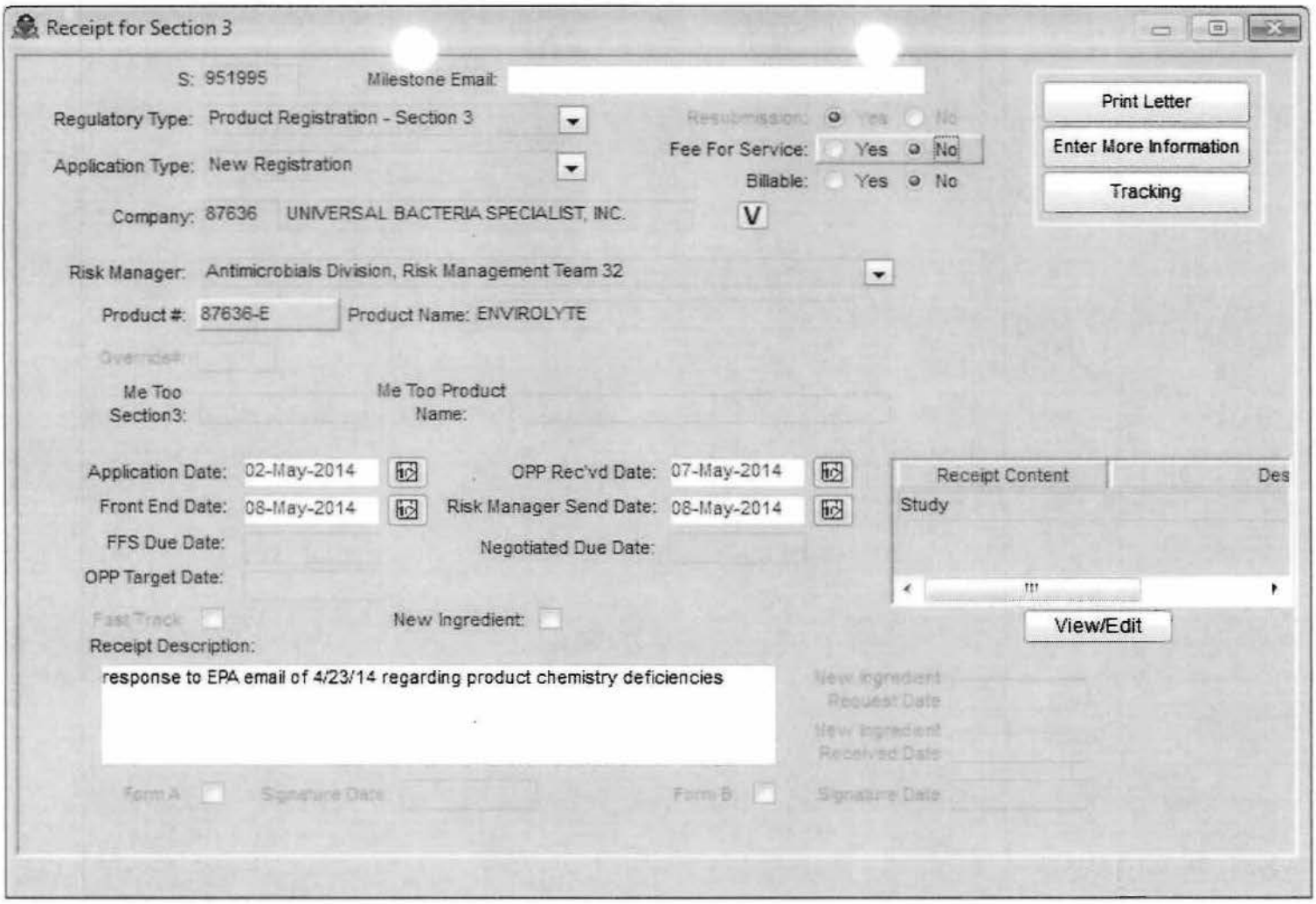
Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 07-MAY-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 11-3, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document. Please use these numbers in all future reference to these documents. Some individual documents were not acceptable. The rejected studies and their deficiencies are described below.

49377301

* A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40CFR160 is required for all studies (except rangefinding studies and supplements to previously submittedstudies) submitted to EPA. This statement must appearas page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.


Receipt for Section 3
S: 951995
Milestone Email:
Regulatory Type: Product Registration - Section 3
Application Type: New Registration
Resubmission: Yes No
Fee For Service: Yes No
Billable: Yes No
Company: 87636 UNIVERSAL BACTERIA SPECIALIST, INC.
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 32
Product #: 87636-E
Product Name: ENVIROLYTE
Me Too Section3:
Me Too Product Name:
Application Date: 02-May-2014
OPP Rec'vd Date: 07-May-2014
Front End Date: 08-May-2014
Risk Manager Send Date: 08-May-2014
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Study
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
response to EPA email of 4/23/14 regarding product chemistry deficiencies
New Ingredient Request Date
New Ingredient Received Date
Form A:
Signature Date
Form B:
Signature Date

49377300

KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
E-mail: kevinkutcel@gmail.com

May 2, 2014

Ms. Wanda Henson (MS- 7510P)
US Environmental Protection Agency
Office of Pesticide Programs
Antimicrobial Division (S-8824)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Envirolyte (Reg. No. 87636-E)

Dear Ms. Henson,

I am responding to your e-mail dated April 23, 2014 in which you forwarded the memo from Ms. Lynette Umez-Eronini dated 4/11/14 pertaining to Reg. No. 87636-E in which she cited several product chemistry deficiencies. Attached are three (3) copies of the amended product chemistry studies in support of Reg. No. 87636-E that are in response to the deficiencies cited by Ms. Umez-Eronini.

49377301
1. Three (3) copies of Product Chemistry Storage Stability (830.6317) and Corrosion Characteristics (830.6320).

49377302
2. Three (3) copies of Product Chemistry Production Process (830.1620); Formulation Process (830.1650); Preliminary Analysis (830.1700) and Enforcement Analytical Method (830.1800).

Your cooperation in reviewing these amended reports in a timely manner is greatly appreciated.

Regards,

Kevin R. Kutcel
Agent for Universal Bacteria Specialists

Sour Wells- **For typical well treatment, slug dose 50 gallons of Envirolyte on a daily or weekly basis to control non-public health microorganisms, reduce hydrogen sulfide gas, and microbial influenced corrosion (MIC).**

Heater Treaters, Hydrocarbon Storage Facilities and Gas Storage Wells – For typical storage facility treatment mix 1 gallon of Envirolyte with 1000 gallons of water to flow through vessels into storage area to retard the growth of non-public health microorganisms, control the formation of hydrogen sulfide, and reduce corrosion of storage tanks.

Use Sites Associated with Gas and Oil Production

Oil and Gas Wells
Plants and Refineries
Pipelines
Hydraulic Fracturing

PRECAUTIONARY STATEMENTS

Physical or Chemical Hazards: Envirolyte is not compatible with other chemicals such as acids and hydrogen peroxide.

ACCEPTED
05/16/2014
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 87636-2

UNIVERSAL BACTERIA SPECIALIST

STORAGE AND DISPOSAL

Do not contaminate water,food, or feed by storage and disposal.

For industrial and commercial use packages:
Pesticide Storage: Store in a closed dark plastic container in cool, dry area away from heat and sunlight. Do not store with easily oxidizable materials, acids and reducers. In case of spill, isolate container (if possible) and flood area with large amounts of water to dissolve all material before discarding this container in trash.
Emergency Handling: In case of contamination or decomposition, do not reseal container. Isolate in open, well-ventilated area. Flood with large volume of water. Cool unopened containers in vicinity by water spray.

Pesticide Disposal: Pesticide wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the EPA Regional Office for guidance.

Small Packages (5 gallons or less):
Container Handling: Nonrefillable rigid container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay clear of smoke.

For Rigid Nonrefillable Containers 5 gallons or more
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Container Handling: REFILLABLE CONTAINER. Refill this container with Envirolyte only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

UNIVERSAL BACTERIA SPECIALIST

ACCEPTED
05/16/2014
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ENVIROLYTE

Aqueous Solution of Sodium Chloride

Envirolyte solutions:

- **are cost effective solutions to produce,**
- **can be produced for multiple industrial and commercial applications,**
- **can be produced with a controlled pH and concentration of Free Available Chlorine (FAC),**
- **are produced with low energy cost from water and salt (sodium chloride)**

ACTIVE INGREDIENT:

Hypochlorous Acid..... 0.105%

OTHER INGREDIENTS..... 99.895%

TOTAL..... 100.000%

Contains 1357 ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN

Reg. No. 87636- **Est. No. 87636-TX-001**

Manufactured by:
Universal Bacteria Specialist
PO Box 570324
Houston, Texas 77257
Ph: 281-342-9555 email cl@universalbacteriaspecialist.com

Envirolyte must be used within 30 days after being produced. DATE PRODUCED:_____

Container Size: (1 gallon, 5 gallon, 55 gallon, 275 gallon tote, 330 gallon tote, 660 gallon tote)

UNIVERSAL BACTERIA SPECIALIST

GENERAL

Envirolyte is produced through the electrolysis of sodium chloride in water. Hypochlorous acid, a weak acid, oxidizing agent, and antimicrobial agent, is produced at the anode. The product at the cathode is sodium hydroxide (lye). In this particular process, Envirolyte is produced at a pH of 6.5 between 6.01 and 8.16.

The properties of Envirolyte can be closely controlled by manipulation of multiple process factors, including the electrolytic cell potential, flow rate, and salt concentration.

Envirolyte will be produced and applied as a liquid with the following physical properties.

- **Freezing point is 32° F**
- **Boiling point is 212°F**
- **Colorless**
- **Slight chlorine odor**

Store Envirolyte in a closed, plastic container in a cool, dark area away from direct sunlight. Envirolyte product must be used within 30 days of production or the FAC (the free available chlorine) will decrease.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

OIL AND GAS APPLICATIONS

Frac Water – For typical water treatment, mix 1.0 gallons of Envirolyte with 1000 gallons of frac water to 1.4 ppm FAC to mitigate and retard the growth of non-public health organisms such as anaerobic bacteria, aerobic bacteria, and sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Produced Waters – For typical treatment of produced water tanks, add 1 gallon of Envirolyte with 1000 gallons of produced water to 1.4 ppm FAC while rolling volume of tank to retard the growth of non-public health organisms such as anaerobic bacteria, aerobic bacteria, and sulfate reducing bacteria.

Water Flood Injection Wells - For typical water treatment, mix 1 gallon of Envirolyte with 1000 gallons of injection water to 1.4 ppm FAC to mitigate and retard the growth of non-public health organisms such as anaerobic bacteria, aerobic bacteria, sulfate reducing bacteria, and control pipeline slime.

UNIVERSAL BACTERIA SPECIALIST

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Plants and Refineries
Pipelines
Hydraulic Fracturing

PRECAUTIONARY STATEMENTS

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UNIVERSAL BACTERIA SPECIALIST

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Emergency Handling: In case of contamination or decomposition, do not reseal container. Isolate in open, well-ventilated area. Flood with large volume of water. Cool unopened containers in vicinity by water spray.

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Container Handling: REFILLABLE CONTAINER. Refill this container with Envirolyte only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

UNIVERSAL BACTERIA SPECIALIST

Henson, Wanda

From: Kevin Kutcel <kevinkutcel@gmail.com>
Sent: Monday, May 19, 2014 2:45 PM
To: Henson, Wanda
Subject: RE: UNIVERSALBBACTERIAL SPECIALISTS

Wanda,

I, Kevin Kutcel, agent, have received the attached document on May 19, 2014 regarding Reg. No. 87635-2. Additionally, I have successfully opened the attachment that accompanied the transmittal email. I am the agent for Universal Bacterial Specialists.

Warm Regards,

Kevin Kutcel
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
Fax: 440-398-0476
E-mail: kevinkutcel@gmail.com

-----Original Message-----
From: Henson, Wanda [mailto:Henson.Wanda@epa.gov]
Sent: Monday, May 19, 2014 2:27 PM
To: Kevin Kutcel
Subject: FW: UNIVERSALBBACTERIAL SPECIALISTS

Henson, Wanda

From: Kevin Kutcel <kevinkutcel@gmail.com>
Sent: Wednesday, May 07, 2014 11:15 AM
To: Henson, Wanda
Cc: Fuller, Demson
Subject: RE: EPA File Symbol No. 87636-E
Attachments: EPA Label Reg no 87636-E 5-7-14.pdf

Wanda,

In response to your e-mail below, attached is a revised label in which the directions for use instructions have been revised to show that the final dilution of the product when used is now less than for Reg. No. 87636-1. Instead of diluting the product to 2.5 ppm, the Envirolyte is diluted 1 gall/1000 gallons of water to 1.4 ppm FAC. This should clarify that the actual exposure to the environment is actually less with this product as compared to the 460 ppm product. I also removed the statement "similar to water" from the label.

To answer your other questions, the product is produced in Houston at Est No. 87636-TX-001 and placed in 275 tote tanks. The product is immediately shipped to the customer and typically used within 2 days. The customer understands that it must be used within 30 days of its production date.

The actual electrolysis mechanism is detailed in the Discussion of Production Process (830.1620) in the product chemistry. It is an electro-chemical reactor, the same as that used to product Reg. No. 87636-1.

Please advise why the signal word, "CAUTION" must be on the label when the acute toxicity data submitted with the application supports category IV?

Warm Regards,

Kevin Kutcel
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
Fax: 440-398-0476
E-mail: kevinkutcel@gmail.com

From: Henson, Wanda [mailto:Henson.Wanda@epa.gov]
Sent: Wednesday, May 7, 2014 10:23 AM
To: Kevin Kutcel
Cc: Fuller, Demson
Subject: EPA File Symbol No. 87636-E

Good Morning,

I have reviewed the EPA registered hypochlorous acid that have the gas and oil applications use patterns. The proposed label must be revised as follows:

1. This product is produced through electrolysis: (1) Who produces it (is it done on site); (2) Where is it produced (at a factory on site); (3) When is it produced considering you only have a 30 days to use it; and (4) What type of electrolysis mechanism is being used.
2. This product claims to be 0.105% Hypochlorous acid, taking in consideration that the highest to date is 0.046% Hypochlorous acid. Please explain how your use directions allot for same amount of product and water to reach the same ppm level as that of the 0.046% solution.
3. Remove the physical properties similar to water information.
4. Add the signal word "CAUTION".

Material Sent for Data Extraction

REG # 87636-2

Description: NEW PRODUCT

Material (s) Sent to Data Extraction Contractors

- [x] New Stamped label Dated: MAY 16, 2014
- [ ] Notification Dated:
- [ ] New CSF(s) Dated:
- [ ] Other:

Decision #:
485380

Other Action/Comments:

Reviewer: Wanda Henson

Phone: 308-6345 **Division:** AD

Date: MAY 19, 2014

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:	Date of Issuance:
87636-2	MAY 16 2014

Term of Issuance: Unconditional

Name of Pesticide Product: ENVIROLYTE

NOTICE OF PESTICIDE:
x Registration
___ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):
Universal Bacterial Specialist
P.O. Box 570324
Houston, TX 77257

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product (OPP Decision No. D-485380) is registered in accordance with FIFRA sec 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Signature of Approving Official:

Demson Fuller
Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

Date: MAY 16 2014

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Demson Fuller
Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosures: (Stamped Label)

ENVIROLYTE

Aqueous Solution of Sodium Chloride

Envirolyte solutions:

- **are cost effective solutions to produce,**
- **can be produced for multiple industrial and commercial applications,**
- **can be produced with a controlled pH and concentration of Free Available Chlorine (FAC),**
- **are produced with low energy cost from water and salt (sodium chloride)**

ACTIVE INGREDIENT:

Hypochlorous Acid..... 0.105%

OTHER INGREDIENTS..... 99.895%

TOTAL..... 100.000%

Contains 1357 ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN

ACCEPTED

05/16/2014

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 87636-2

Reg. No. 87636- **Est. No. 87636-TX-001**

Manufactured by:
Universal Bacteria Specialist
PO Box 570324
Houston, Texas 77257
Ph: 281-342-9555 email cl@universalbacteriaspecialist.com

Envirolyte must be used within 30 days after being produced. DATE PRODUCED:_____

Container Size: (1 gallon, 5 gallon, 55 gallon, 275 gallon tote, 330 gallon tote, 660 gallon tote)

UNIVERSAL BACTERIA SPECIALIST

GENERAL

Envirolyte is produced through the electrolysis of sodium chloride in water. Hypochlorous acid, a weak acid, oxidizing agent, and antimicrobial agent, is produced at the anode. The product at the cathode is sodium hydroxide (lye). In this particular process, Envirolyte is produced at a pH of 6.5 between 6.01 and 8.16.

The properties of Envirolyte can be closely controlled by manipulation of multiple process factors, including the electrolytic cell potential, flow rate, and salt concentration.

Envirolyte will be produced and applied as a liquid with the following physical properties.

- **Freezing point is 32° F**
- **Boiling point is 212°F**
- **Colorless**
- **Slight chlorine odor**

Store Envirolyte in a closed, plastic container in a cool, dark area away from direct sunlight. Envirolyte product must be used within 30 days of production or the FAC (the free available chlorine) will decrease.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

OIL AND GAS APPLICATIONS

Frac Water – For typical water treatment, mix 1.0 gallons of Envirolyte with 1000 gallons of frac water to 1.4 ppm FAC to mitigate and retard the growth of non-public health organisms such as anaerobic bacteria, aerobic bacteria, and sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Produced Waters – For typical treatment of produced water tanks, add 1 gallon of Envirolyte with 1000 gallons of produced water to 1.4 ppm FAC while rolling volume of tank to retard the growth of non-public health organisms such as anaerobic bacteria, aerobic bacteria, and sulfate reducing bacteria.

Water Flood Injection Wells - For typical water treatment, mix 1 gallon of Envirolyte with 1000 gallons of injection water to 1.4 ppm FAC to mitigate and retard the growth of non-public health organisms such as anaerobic bacteria, aerobic bacteria, sulfate reducing bacteria, and control pipeline slime.

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ACCEPTED

05/16/2014

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 87636-2

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UNIVERSAL BACTERIA SPECIALIST

Material Sent for Data Extraction

REG # 87636-2

Description: Notification

Material (s) Sent to Data Extraction Contractors

- ☐ New Stamped label Dated:
- ☑ Notification Dated: 07/17/14
- ☐ New CSF(s) Dated:
- ☐ Other:

Decision #:

Other Action/Comments:

Reviewer: Wanda Henson

Phone: 703-308-6345 **Division:** AD

Date: 08/18/14

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

JUL 17 2014

Kevin R. Kutcel
KRK Consulting, LLC
5807 Churchill Way
Medina, OH 44256

Subject:	Universal Bacteria Specialist Envirolyte
EPA Reg. No.	87636-2
Application Date:	June 13, 2014
Receipt Date:	June 18, 2014

Dear Mr. Kutcel:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification:

- For an alternate brand name (Environlyte O&G)

General Comments:

Based on a review of the material submitted, the following comment applies:

The notification application is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at Henson.Wanda@epa.gov or call (703) 308-6345.

Sincerely,

Wanda Y. Henson
Environmental Protection Specialist
Regulatory Management Branch II
Antimicrobials Division (7510P)

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

United States Environmental Protection Agency Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: Universal Bacteria Specialist / 87636-2
2. EPA Product Manager: Demson Fuller
3. Proposed Classification: [x] None [ ] Restricted
4. Company/Product (Name): Universal Bacteria Specialist /Envirolyte
PM#:
5. Name and Address of Applicant (Include ZIP Code)
Universal Bacteria Specialist
PO Box 570324
Houston, TX 77257
[ ] Check if this is a new address
6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [x] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Please see cover letter.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No		[ ] Yes [x] No		[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	

3. Location of Net Contents Information: [x] Label [ ] Container
4. Size(s) Retail Container: 1,5,55,275,330,660 gall
5. Location of Label Directions: [ ] On Label [ ] On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: [x] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name	Title	Telephone No. (Include Area Code)
Kevin R. Kutcel	Agent	440-263-7305

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
[signature]	Agent
4. Typed Name	**5. Date**
Kevin R. Kutcel	Jun 13, 2014

KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
E-mail: kevinkutcel@gmail.com

June 16, 2014

US EPA (NOTIF)
Office of Pesticide Programs
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: PR Notice 1998-10 Notification for ABN (EPA No. 87636-2)

Please accept the attached 3 copies of the revised label for Reg. No. 87636-2 with the alternate brand name "Envirolyte O&G" per PR Notice 1998-10.

Attached is EPA Form 8570-1 regarding this notification as required in PR Notice 1998-10. This notification is consistent with the guidance in PR Notice 1998-10 and the requirements of EPA's regulations at 40 CFR 156.46, 156.140, 156.144, 156,146 and 156.156 and no other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand this it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of PR Notice 98-10 and CFR 156.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Please note that KRK Consulting LLC is the authorized agent handling all correspondence for Universal Bacteria Specialists and therefore all responses should be directed to the contact information on the letterhead above.

Best Regards,

Kevin R. Kutcel,
Agent for Universal Bacteria Specialists

ENVIROLYTE O & G

Aqueous Solution of Sodium Chloride

Envirolyte O & G solutions:

- **are cost effective solutions to produce,**
- **can be produced for multiple industrial and commercial applications,**
- **can be produced with a controlled pH and concentration of Free Available Chlorine (FAC),**
- **are produced with low energy cost from water and salt (sodium chloride)**

ACTIVE INGREDIENT:

Hypochlorous Acid..... 0.105%
OTHER INGREDIENTS..... 99.895%
TOTAL..... 100.000%

Contains 1357 ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN

Reg. No. 87636-2 **Est. No. 87636-TX-001**

Manufactured by:
Universal Bacteria Specialist
PO Box 570324
Houston, Texas 77257
Ph: 281-342-9555 email cl@universalbacteriaspecialist.com

Envirolyte O & G must be used within 30 days after being produced. DATE PRODUCED:_____

Container Size: (1 gallon, 5 gallon, 55 gallon, 275 gallon tote, 330 gallon tote, 660 gallon tote)

UNIVERSAL BACTERIA SPECIALIST

GENERAL

Envirolyte O & G is produced through the electrolysis of sodium chloride in water. Hypochlorous acid, a weak acid, oxidizing agent, and antimicrobial agent, is produced at the anode. The product at the cathode is sodium hydroxide (lye). In this particular process, Envirolyte O & G is produced at a pH of 6.5 between 6.01 and 8.16.

The properties of Envirolyte O & G can be closely controlled by manipulation of multiple process factors, including the electrolytic cell potential, flow rate, and salt concentration.

Envirolyte O & G will be produced and applied as a liquid with the following physical properties.

- **Freezing point is 32° F**
- **Boiling point is 212°F**
- **Colorless**
- **Slight chlorine odor**

Store Envirolyte O & G in a closed, plastic container in a cool, dark area away from direct sunlight. Envirolyte O & G product must be used within 30 days of production or the FAC (the free available chlorine) will decrease.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

OIL AND GAS APPLICATIONS

Frac Water – For typical water treatment, mix 1.0 gallons of Envirolyte O & G with 1000 gallons of frac water to 1.4 ppm FAC to mitigate and retard the growth of non-public health organisms such as anaerobic bacteria, aerobic bacteria, and sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Produced Waters – For typical treatment of produced water tanks, add 1 gallon of Envirolyte O & G with 1000 gallons of produced water to 1.4 ppm FAC while rolling volume of tank to retard the growth of non-public health organisms such as anaerobic bacteria, aerobic bacteria, and sulfate reducing bacteria.

Water Flood Injection Wells - For typical water treatment, mix 1 gallon of Envirolyte O & G with 1000 gallons of injection water to 1.4 ppm FAC to mitigate and retard the growth of non-public health organisms such as anaerobic bacteria, aerobic bacteria, sulfate reducing bacteria, and control pipeline slime.

UNIVERSAL BACTERIA SPECIALIST

Sour Wells- For typical well treatment, slug dose 50 gallons of Envirolyte O & G on a daily or weekly basis to control non-public health microorganisms, reduce hydrogen sulfide gas, and microbial influenced corrosion (MIC).

Heater Treaters, Hydrocarbon Storage Facilities and Gas Storage Wells – For typical storage facility treatment mix 1 gallon of Envirolyte O & G with 1000 gallons of water to flow through vessels into storage area to retard the growth of non-public health microorganisms, control the formation of hydrogen sulfide, and reduce corrosion of storage tanks.

Use Sites Associated with Gas and Oil Production

Oil and Gas Wells
Plants and Refineries
Pipelines
Hydraulic Fracturing

PRECAUTIONARY STATEMENTS

Physical or Chemical Hazards: Envirolyte O & G is not compatible with other chemicals such as acids and hydrogen peroxide.

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STORAGE AND DISPOSAL

Do not contaminate water,food, or feed by storage and disposal.

For industrial and commercial use packages:
Pesticide Storage: Store in a closed dark plastic container in cool, dry area away from heat and sunlight. Do not store with easily oxidizable materials, acids and reducers. In case of spill, isolate container (if possible) and flood area with large amounts of water to dissolve all material before discarding this container in trash.
Emergency Handling: In case of contamination or decomposition, do not reseal container. Isolate in open, well-ventilated area. Flood with large volume of water. Cool unopened containers in vicinity by water spray.

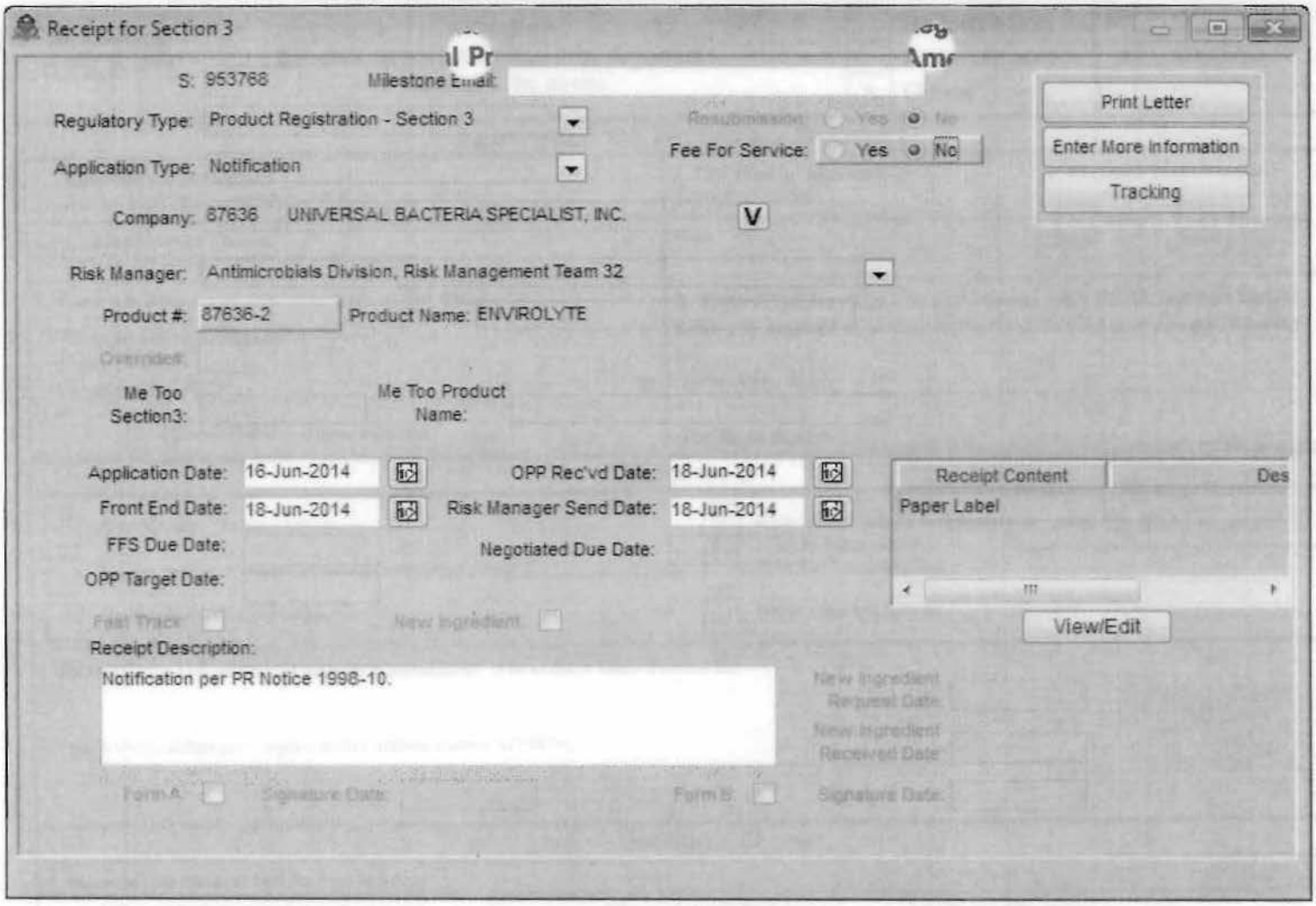
Pesticide Disposal: Pesticide wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the EPA Regional Office for guidance.

Small Packages (5 gallons or less):
Container Handling: Nonrefillable rigid container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay clear of smoke.

For Rigid Nonrefillable Containers 5 gallons or more
Container Handling: Nonrefillable rigid container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning if available or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay clear of smoke.

Container Handling: REFILLABLE CONTAINER. Refill this container with Envirolyte **O & G** only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

UNIVERSAL BACTERIA SPECIALIST


Receipt for Section 3
S: 953766
Milestone Email:
Regulatory Type: Product Registration - Section 3
Application Type: Notification
Resubmission: Yes No
Fee For Service: Yes No
Print Letter
Enter More Information
Tracking
Company: 87636 UNIVERSAL BACTERIA SPECIALIST, INC.
V
Risk Manager: Antimicrobials Division, Risk Management Team 32
Product #: 87636-2
Product Name: ENVIROLYTE
Me Too Section3:
Me Too Product Name:
Application Date: 16-Jun-2014
OPP Rec'vd Date: 18-Jun-2014
Front End Date: 18-Jun-2014
Risk Manager Send Date: 18-Jun-2014
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Paper Label
View/Edit
Fast Track:
New Ingredient:
Receipt Description:
Notification per PR Notice 1998-10.
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

United States Environmental Protection Agency Washington, DC 20460

☐ Registration ☐ Amendment ☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Universal Bacteria Specialist / 87636-2	Demson Fuller	☒ None ☐ Restricted
4. Company/Product (Name) Universal Bacteria Specialist /Envirolyte	PM#	

5. Name and Address of Applicant *(Include ZIP Code)*

Universal Bacteria Specialist
PO Box 570324
Houston, TX 77257

☐ *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated _____

☐ Notification - Explain below.

☒ Final printed labels in response to Agency letter dated May 19, 2014

☐ "Me Too" Application.

☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Final printed label per registration notice dated 5/19/14.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information ☒ Label ☐ Container

4. Size(s) Retail Container 1,5,55,275,330,660 gal

5. Location of Label Directions ☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☒ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Kevin R. Kutcel	Agent	440-263-7305

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
[signature]	Agent
4. Typed Name Kevin R. Kutcel	**5. Date** Jun 13, 2014

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

FOR OFFICIAL USE ONLY

FILE SYMBOL
REGISTRATION NO.

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER

Do Not Write Comments, Formula, or Parts of Formula on This Envelope

NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

Pages 106-109 Confidential Statement of Formula may be entitled to confidential treatment